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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 008--Autoimmune Diseases; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On May 11, 2015, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 008) to add autoimmune diseases to the List of WTC-Related Health Conditions (List). Upon reviewing the information provided by the petitioner, the Administrator has determined that Petition 008 is not substantially different from Petition 007, which also requested the addition of autoimmune diseases. The Administrator recently published a response to Petition 007 in the Federal Register and has determined that Petition 008 does not provide additional evidence of a causal relationship

between 9/11 exposures and autoimmune diseases.

Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII¹ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 60

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (i) Request a recommendation of the STAC; (ii) publish a proposed rule in the Federal Register to add such health condition; (iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the Federal Register a determination that insufficient evidence exists to take action under (i) through (iii) above. However, in accordance with 42 CFR 88.17(a)(4), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis -- evidence not previously reviewed by the Administrator -- for the association between 9/11 exposures and the condition to be added.

B. Petition 008

On May 11, 2015, the Administrator received a petition to add "autoimmune disease -- encephalitis of the brain" to

the List (Petition 008).² This is the second petition to the Administrator requesting the addition of autoimmune diseases to the List; the first autoimmune disease petition, Petition 007, was denied due to insufficient evidence as described in a Federal Register notice published on June 8, 2015 (80 FR 32333). Petition 008, which is addressed in this notice, was submitted by a WTC Health Program member who responded to the September 11, 2001, terrorist attacks in New York City. The petitioner indicated that she has been diagnosed with encephalitis as well as two WTC-related health conditions. The petition presented as evidence several newspaper articles referencing a study recently published in the Journal of Arthritis and Rheumatology by Webber et al. [2015],³ which was designed to test the hypothesis that acute and chronic 9/11 work-related exposures were associated with the risk of certain new-onset systemic autoimmune diseases.

Although Petition 008 specifically requested the addition of "autoimmune disease -- encephalitis of the brain," the Administrator determined that the scope of the petition properly includes only the autoimmune diseases

² See Petition 008. WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

³ Webber MP, Moir W, Zeig-Owens R, Glaser MS, Jaber N, Hall C, Berman J, Qayyum B, Loupasakis K, Kelly K, and Prezant DJ [2015]. Nested case-control study of selected systemic autoimmune diseases in World Trade Center rescue/recovery workers. Journal of Arthritis & Rheumatology 67(5):1369-1376.

identified in Webber et al., cited as evidence in both Petition 007 and Petition 008.⁴ Encephalitis is not among the autoimmune diseases studied by Webber et al. No other evidence was provided in Petition 008 to support the addition of encephalitis to the List; therefore, encephalitis is not addressed in this action.

C. Administrator's Determination on Petition 008

The Administrator has established a methodology for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program website.⁵ However, the Administrator has determined that the methodology is not triggered in this case because Petition 008 requested the addition of a health condition that was previously reviewed by the Program, and presented no new evidence of a causal association between 9/11 exposures and autoimmune diseases. In a response to Petition 007, which also requested the addition of autoimmune diseases, published in the Federal Register on June 8, 2015 (80 FR 32333), the Administrator reviewed the findings presented in the Webber study and determined that

⁴ This determination is consistent with the Administrator's reasoning in the Petition 007 finding of insufficient evidence. 80 FR 32333, June 8, 2015.

⁵ "Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions," John Howard MD, Administrator of the WTC Health Program, October 21, 2014. http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.

insufficient evidence exists to take any of the following actions: propose the addition of autoimmune diseases to the List (pursuant to PHS Act, section 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)); publish a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, section 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)); or request a recommendation from the STAC (pursuant to PHS Act, section 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)). Because the Administrator recently evaluated the Webber study, presented as evidence for the addition of autoimmune conditions in Petition 007, there is no need to reevaluate the same evidence again in response to the request to add autoimmune diseases in Petition 008, which also presented the Webber study as evidence of a causal association between 9/11 exposures and autoimmune diseases.

Accordingly, with regard to Petition 008, the Administrator has determined that insufficient evidence exists to take further action, including either proposing the addition of autoimmune diseases to the List (pursuant to PHS Act, section 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, section 3312(a)(6)(B)(iii) and 42 CFR

88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, section 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 008 to add autoimmune diseases to the List of WTC-Related Health Conditions is denied.

The Administrator is aware that another study of autoimmune diseases among WTC Health Program members is being conducted by the WTC Health Registry; however, results from this study are not yet available in the scientific literature. The Administrator will monitor the scientific literature for publication of the results of this study and any other studies that address autoimmune diseases among 9/11-exposed populations.

Dated: July 1, 2015.

John Howard, M.D.

Administrator, World Trade Center Health Program and
Director, National Institute for Occupational Safety and
Health, Centers for Disease Control and Prevention,
Department of Health and Human Services

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